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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,310	04/13/2006	Donald W. Landry	60919-PCT-US	5430

23432 7590 05/24/2007
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EXAMINER	
BRADLEY, CHRISTINA	
ART UNIT	**PAPER NUMBER**
1654	
MAIL DATE	**DELIVERY MODE**
05/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,310	LANDRY ET AL.	
	Examiner	Art Unit	
	Christina Marchetti Bradley	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-11,13,14,16-19,21,28,30,31,35,36 and 39-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,16-19,21,28,30,31 and 39-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-7,9-11,13,35 and 36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/9/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's arguments, see page 10, filed 2/12/2007, with respect to the restriction requirement have been fully considered and are persuasive. The cited reference Cho *et al.* does not teach a peptide that forms a phosphorous-based ester with an organophosphorous agent. Catalysis of organophosphorous hydrolysis by OP hydrolase proceeds by an S_N2 mechanism in which water, the nucleophile, is activated by the enzyme active site residues (general acid/base catalysis); a covalent intermediate between the enzyme and substrate is not formed. Therefore, the restriction requirement has been withdrawn. However, upon further consideration, a new ground(s) for restriction is made.

2. Restriction is required under 35 U.S.C. 121 and 372.

3. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

4. Group I, claim(s) 1-7, 9-11 and 13, drawn to methods for determining whether a peptide forms a phosphorous-based ester with an organophosphorous agent.

5. Group II, claim(s) 14, 16-19, 21, 28, 30, 31, and 39-41, drawn to peptides that form a phosphorous-based ester with an organophosphorous agent and compositions and libraries thereof.

6. Group III, claim(s) 35 and 36, drawn to methods for treating exposure to or decontaminating an area exposed to an organophosphorous agent.

7. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: peptides that form a phosphorous-based ester with organophosphorous agents and their use as scavengers of such agents are known in the prior art (LeJeune *et al.*, *Ann. N.Y. Acad. Sci.*, **1998**, *864*, 153-70, cited reference number 16 on Information Disclosure Statement mailed 6/09/2005). See Figure 2 for evidence of a peptide, AChE, that forms a phosphorous-based ester with the organophosphorous agent sarin and page

156, third full paragraph for discussion of the use of AChE as a nerve agent scavenger. Therefore, unity of invention is lack *a posteriori.*

8. In the response filed 2/12/2007, applicant elected, with traverse, previous group II. Therefore, an examination on the merits of group II listed above (claims 14, 16-19, 21, 28, 30, 31, and 39-41), which encompasses previous groups II-IV, appears below. Claims 1-7, 9-11, 13, 35 and 36 are withdrawn.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 14, 16-19, 21, 28, 30, 31, and 39-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

11. Claims 14, 16-19, 21, 28, 30, 31, and 39-41are drawn to peptides that form a phosphorous-based ester with an organophosphorous agent. The specification discloses the complete structure of SEQ ID NOs: 1-11. The claimed genus is much broader than this well-defined subgenus. The minimal structural requirements for the genus are that the peptide

comprise a functional group capable of forming an ester with an organophosphorous agent, i.e. a thiol or hydroxyl, and for claims 16-18, that the peptide be between 6 and 15 amino acids long. An infinite number of peptide sequences could satisfy these minimal requirements. Despite this breadth, the specification does not disclose the complete or partial structure or chemical/physical properties of any additional peptides, or guidance on how to obtain specific peptides with the claimed functional properties of forming a phosphorous-based ester with an organophosphorous agent. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Regarding claim 21, only the hexapeptide library recited on page 23 of the specification is described.

12. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). With the exception of SEQ ID NOs: 1-11, and for claim 21 the hexapeptide library recited on page 23 of the specification, the skilled artisan cannot envision the detailed chemical structure of the invention. Although the minimal structural requirements of the genus are defined, there are too many undefined structural features for the skilled artisan to envision its full scope. Therefore, only SEQ ID NOs: 1-11, and for claim 21 the hexapeptide library recited on page 23 of the specification, but not the full breadth of the claims, meet the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 14, 19, 28, 30, 31 and 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by LeJeune *et al.* (LeJeune *et al.*, *Ann. N.Y. Acad. Sci.*, **1998**, *864*, 153-70, cited reference number 16 on Information Disclosure Statement mailed 6/09/2005). LeJeune *et al.* teach peptides that form a phosphorous-based ester with an organophosphorous agent and their use as scavengers of such agents. Figure 2 depicts a peptide, AChE, that forms a phosphorous-based ester with the organophosphorous agent sarin and page 156, third full paragraph discusses the use of AChE as a nerve agent scavenger, satisfying the limitations of claims 14, 19 and 40. Regarding claim 39, AChE comprises a hydroxyl functional group (figure 2). Regarding claims 28, 30 and 41, LeJeune *et al.* teach AChE as part of a foam composition (pages 167-8, Table 2a). Regarding claim 31, LeJeune *et al.* teach the immobilization of AChE on solid substrates (pages 167-8).

15. Claims 14, 19, 28 and 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Stewart *et al.* (*Science*, **1998**, *279*, 1534-41). Stewart *et al.* teach a peptide, human topoisomerase I, that forms a phosphorous-based ester with an organophosphorous agent. DNA strand cleavage by human topoisomerase I involves nucleophilic attack by a catalytic tyrosine

residue on the scissile phosphodiester bond of the DNA that culminates in the formation of a covalent intermediate between the enzyme and DNA (page 1534, first column, and figure 3). Regarding claims 28 and 41, the topoisomerase I is included in a composition (Table 1). Regarding claim 39, the side chain responsible for forming the covalent link with DNA is tyrosine which comprises a hydroxyl group.

16. Claims 14, 16-19, 39 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Landry (U.S. Patent No. 5,948,658). Landry teaches the peptides SDYAWT (SEQ ID NO: 46) and SDYAWN (SEQ ID NO: 52) which consist of 6 amino acids (claims 16 and 17), are less than 1500 Daltons in molecular weight (claim 18) and contain a hydroxyl functional group (claim 39).

17. Claims 14, 16, 18, 19, 21, 28, 31 and 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by the Ph.D.-C7C Disulfide Constrained Peptide Library Kit sold by New England Biolabs (product number 8120. New England Biolabs Catalog, 1998/99, pp. 140-1). The library comprises randomized heptapeptide sequences flanked by a pair of cysteine residues at the N- and C-termini (page 140, second column). Thus, the library comprises peptides between 6 and 15 residues in length (satisfying claim 16) and less than 1500 Daltons in molecular weight (satisfying claim 18) that because of their thiol functional groups (satisfying claim 39) are capable of forming a phosphorous-based ester with an organophosphorous agent (satisfying claim 14). Regarding claims 28 and 41, the libraries are provided as a composition with a carrier. Regarding claim 31, the New England Biolabs catalog teaches that the peptides can be fixed to a solid substrate during a biopanning experiment (figure 1).

18. Claims 14, 16-19, 21, 28, 31 and 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Dower *et al.* (U.S. Patent No. 5,432,018). Dower *et al.* teach a hexapeptide library comprises all possible randomized heptapeptide sequences (Example 1). Thus, the library comprises peptides of 6 residues in length (satisfying claims 16 and 17) and is less than 1500 Daltons in molecular weight (satisfying claim 18). Because the library includes all possible sequences it must include hydroxyl and thiol functional groups (satisfying claim 39). Regarding claims 28 and 41, the libraries are provided as a composition with a carrier. Regarding claim 31, the peptides can be fixed to a solid substrate during a panning experiment (example 1).

19. Regarding claims 19 and 40, neither Stewart *et al.*, Landry, New England Biolabs Catalog or Dower *et al.* teach that the respective peptides form a phosphorous-based ester with an insecticide or chemical warfare agent. Because the chemical structure of the species taught by Stewart *et al.*, Landry and the New England Biolabs Catalog are identical to the claimed invention, there is a reasonable expectation that the species would meet this additional functional limitation. The discovery and characterization of properties of a known material do not make it novel (see MPEP § 2112). Furthermore, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference (see MPEP § 2112).

20. If the composition is physically the same, it must have the same functional properties. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) See MPEP §

2112.01. Examiner cannot however determine whether or not the peptides taught by Stewart *et al.*, Landry, the New England Biolabs Catalog or Dower *et al.* inherently possess properties which anticipate or render obvious the claimed invention but has basis for shifting the burden of proof to applicant as in In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See MPEP § 2112.

Double Patenting

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
22. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
23. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

24. Claims 14, 19, 28, and 39-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,913,917. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 14, 19, 28, and 39-41 are generic to all that is recited in claims 1-3 of U.S. Patent No. 6,913,917. That is claims 1-3 of U.S. Patent No. 6,913,917 fall entirely within the scope of claims 14, 19, 28, and 39-41 or, in other words, claims 14, 19, 28, and 39-41 are anticipated by

claims 1-3 of U.S. Patent No. 6,913,917. Specifically, claims 1-3 recite a humanized catalytic antibody comprising the light chain sequence RSSXGTITXXNYAN and pharmaceutical compositions comprising it. Because the peptide comprises several hydroxyl functional groups, it is inherently capable of forming a phosphorous-based ester with an organophosphorous agent.

25. Claims 14, 19, 28, and 39-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 5,948,658. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 14, 19, 28, and 39-41 are generic to all that is recited in claims 1-14 of U.S. Patent No. 5,948,658. That is claims 1-14 of U.S. Patent No. 5,948,658 fall entirely within the scope of claims 14, 19, 28, and 39-41 or, in other words, claims 14, 19, 28, and 39-41 are anticipated by claims 1-14 of U.S. Patent No. 5,948,658. Specifically, claims 1-12 recite a catalytic antibody comprising the light chain sequence RSSXGTITXXNYAN and pharmaceutical compositions comprising it; claims 13 and 14 recite a catalytic antibody comprising the light chain sequence KSSQSLLYSDGKTYLN. Because the peptides comprises several hydroxyl functional groups, they are inherently capable of forming a phosphorous-based ester with an organophosphorous agent.

26. Claims 14, 19, 28, and 39-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,280,987. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 14, 19, 28, and 39-41 are generic to all that is recited in claims 1-23 of U.S. Patent No. 6,280,987. That is claims 1-23 of U.S. Patent No. 6,280,987 fall entirely within the scope of claims 14, 19, 28, and 39-41 or, in other words, claims 14, 19, 28, and 39-41 are anticipated by

claims 1-23 of U.S. Patent No. 6,280,987. Specifically, claims 1-7 and 21 recite a catalytic antibody comprising the light chain sequence RSSXGTITXXNYAN; claims 8, 9 and 22 recite a catalytic antibody comprising the light chain sequence KSSQSLLYSDGKTYLN; claims 10 and 13-18 recite a catalytic antibody comprising the light chain sequence RSSXSLLYXDGKTYLN; claims 11 and 12 recite a catalytic antibody comprising the light chain sequence RSSRSLLYRDGKTYLN; and claims 19, 20 and 23 recite a catalytic antibody comprising the light chain sequence KSSQSLLYSDGKTYLN . Because the peptides comprises several hydroxyl functional groups, they are inherently capable of forming a phosphorous-based ester with an organophosphorous agent.

Conclusion

27. No claims are allowed.
28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Marchetti Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.
29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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